

K021467

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

NOV 4 2002

Contact:

James A. Lee
Regulatory Affairs Specialist

Device Identification:

Common Name:

Electrosurgical Generator

Trade Name: (optional)

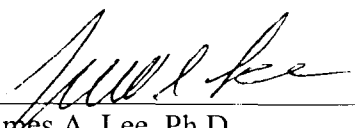
The KSEA Autocon II 400 Electrosurgical Generator

Indication: The Autocon II 400 Electrosurgical Generator is intended for use by qualified surgeons to provide a high frequency (HF) electrical current for cutting and coagulating tissue during open and endoscopic surgeries, including general, plastic, urological, neurological, and gynecologic procedures.

Device Description: The Autocon II 400 consists of a generator, a dual pedal foot switch, and a power cord. The footswitch activates the power for cutting and coagulation. The Autocon II 400 is able to provide either monopolar or bipolar modes for cutting and coagulation. It can be linked to Karl Storz SCB.

Substantial Equivalence: The KSEA Autocon II 400 Electrosurgical Generator is substantially equivalent to the predicate devices since the basic design, dimensions, safety features, and intended uses are similar. The minor differences between the KSEA Autocon II 400 Electrosurgical Generator and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: _____


James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2002

Karl Storz Endoscopy-America, Inc
James A. Lee
Senior Regulatory Affairs Specialist
600 Corporate Pointe
Culver City, California 90230-7600

Re: K021467

Trade/Device Name: Autocon II 400 Electrosurgical Generator
Regulation Number: 878.4400
Regulation Name: Electrosurgical probe
Regulatory Class: Class II
Product Code: GEI
Dated: September 11, 2002
Received: September 12, 2002

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

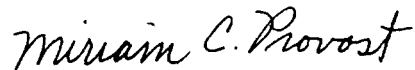
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. James A. Lee

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K 021467

510(k) Number (if known): Not yet assigned.

Device Name: Autocon II 400 Electrosurgical Generator

Indications for Use: The Autocon II 400 Electrosurgical Generator is intended for use by qualified surgeons to provide a high frequency (HF) electrical current for cutting and coagulating tissue during open and endoscopic surgeries, including general, plastic, urological, neurological, and gynecologic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 021467